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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SIMS, JASON M

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/688,255	Applicant(s) AEHLE ET AL.	
	Examiner Jason M. Sims	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-15 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/15/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election of group I, claims 1-15, in the reply filed on 8/21/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's withdrawing of claim 6 in the response filed on 8/21/2006 is acknowledged.

Applicant's cancellation of claims 16-18 in the response filed on 8/21/2006 is acknowledged.

Claims 1-5 and 7-15 are the current claims hereby under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-5 and 7-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 step d contains the wording "combinatorial consensus library," which is vague and indefinite as to what it refers. For example, the "combinatorial consensus library" may contain consensus sequences, consensus mutations themselves, or sequences that contain the consensus mutations. It is vague and indefinite as to what comprises the "combinatorial consensus library" or what it means. Appropriate correction is required.

Claim 1 step e is vague and indefinite. Claim 1 step e contains the wording, "initial hit." The specification defines an "initial hit" as "a variant that was identified by screening a combinatorial consensus mutagenesis library." Step d of method claim 1, recites producing a combinatorial consensus library, not a combinatorial consensus **mutagenesis** library. Therefore, based on the definition of "initial hit," it is deemed vague and indefinite as to how the result of step e of identifying at least one "initial hit" could occur when step d of method claim 1 does not appear to produce the required combinatorial consensus **mutagenesis** library, but instead produces a combinatorial consensus library.

Claim 1, step d, cites production of a combinatorial consensus library. It is vague and indefinite as to whether this production is wet, such as in the production of actual vectors, which comprise the library, or is dry, such as in the electronic data production of such a library. Clearer claim wording is required.

Claim 3 step b is vague and indefinite. It is unclear as to what function screening a library, which is produced only from enhanced combinatorial sequences, as in claim 3 step a, would serve for identifying at least one improved hit. It appears that all sequences found in the newly produced combinatorial consensus library from enhanced consensus sequences will only contain improved hits. Therefore, step b is unclear as to what its function does. Clearer claim wording is required.

Claims 2-4 and 7-15 are rejected as being dependent from a rejected claim.

Claim Rejections - 35 USC § 101

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35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Under the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published in the O.G. notice (1300 OG 142) on 11/22/2005) a method that does not result in a physical transformation of matter MAY be statutory where it recites a concrete, tangible and useful result; i.e. a practical application.

Claim 1 is drawn to a method/process. A statutory process must include a step of a physical transformation, or produce a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999))). In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

As noted in State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998) below, the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result:

The question of whether a claim encompasses statutory subject matter should not focus on *which* of the four categories of subject matter a claim is directed to 9-- process, machine, manufacture, or composition of matter--but rather on the essential characteristics of the subject matter, in particular, its practical utility. Section 101

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specifies that statutory subject matter must also satisfy the other "conditions and requirements" of Title 35, including novelty, nonobviousness, and adequacy of disclosure and notice. See *In re Warmerdam*, 33 F.3d 1354, 1359, 31 USPQ2d 1754, 1757-58 (Fed. Cir. 1994). For purpose of our analysis, as noted above, claim 1 is directed to a machine programmed with the Hub and Spoke software and admittedly produces a "useful, concrete, and tangible result." *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557. This renders it statutory subject matter, even if the useful result is expressed in numbers, such as price, profit, percentage, cost, or loss.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claim 1 does not produce a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or a memory or another computer on a network, or outputting the result to a user, or by including a physical transformation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1- 5 and 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Crameri et al. (US P/N 6, 368, 861).

The claims are directed to a method for combinatorial consensus mutagenesis comprising of starting with a gene of interest, identifying homologs, aligning the sequences to identify consensus mutations, produce a combinatorial consensus library, and screen the library for an initial hit.

Crameri et al. teaches claim 1 and 10 at col. 2, lines 49-53, col. 4, lines 33-37, col. 7, lines 29-36, col. 8, lines 65-67, col. 9, lines 1-7 and lines 35-52, col. 10, lines 62-67, col. 11, and col. 13 lines 10-12. Crameri et al, at col. 7 discusses using oligonucleotides corresponding to at least one region of diversity, which represents selecting a gene of interest. Crameri et al., at col. 7-11, further discusses aligning nucleic acid sequences using available computer software and specifically at col. 9, Crameri et al. discusses using BLAST and other specific alignment algorithms and tools, which represents generating a multiple sequence alignment of at least two homologs and a starting gene of interest. Crameri et al., at col. 2, discusses a method that provides a population of recombined nucleic acids where the members have consensus region subsequences derived from a plurality of homologous target nucleic acids, which represents a production of a combinatorial consensus library. Crameri et al. at col. 13 discusses screening methods for the combinatorial library. Crameri et al. at col. 4 discusses the said methods for homologous target sequences in regions that

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are overlapping or non-overlapping, which represents regions of homologs that are not part of a consensus sequence.

Crameri et al. teaches claims 2-4 and 11-14 at col. 10 and col. 13, lines 42-57. Crameri et al. discusses producing and sequencing improved clones from the cited inventive methods and producing a library of said improved clones, which represents sequencing at least one initial hit, identifying improving mutations and generating enhanced combinatorial consensus libraries and sequencing improved hits. Crameri et al. discusses doing the performing the above methods multiple times until desired properties result, which represents performing the methods of claims 2 and 3 more than once and producing improved sequence hits according to methods of claims 2 and 3.

Crameri et al. teaches claim 5 at col. 33, lines 55-67 and col. 34, lines 1-6. Crameri et al. discusses screening techniques that depend on what property or characteristic is desired such as stability-conferring sequences, which represents hits that are stabilized variants of said starting gene.

Crameri et al. teaches claim 15 at col. 4, lines 10-15, col. 8, lines 35-38, col. 10, lines 63-67, col. 11, and col. 12, lines 1-11. Crameri et al. discusses the products and compositions resulting from above said methods such as a library of nucleotides as discussed, which represents the production of a combinatorial consensus mutagenesis library according to the method of claim 1 of the instant application.

Conclusion

No claim is allowed

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang can be reached via telephone (571)-272-0811.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

John S. Brusca 9 November 2006

JOHN S. BRUSCA, PH.D. JOHN S. BRUSCA, PH.D.
PRIMARY EXAMINER PRIMARY EXAMINER